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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/242,843	11/18/99	JARRETT	P

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EXAMINER
MCGARRY, S

ART UNIT	PAPER NUMBER
1635	16

DATE MAILED: 03/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/242,843	JARRETT ET AL.	
	Examiner	Art Unit	
	Sean McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1/36* is/are pending in the application.

4a) Of the above claim(s) *15,16 and 21-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

1. The information disclosure statement filed 1/31/~~200~~ 2001 up fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the reference cited as "B2" is not in the English language and no explanation of the relevance is provided. It has been placed in the application file, but the information referred to therein as "B2" has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

2. Applicant's election with traverse of Group I in Paper No. 15, filed 1/16/01. is acknowledged. The traversal is on the ground(s) that the special technical feature linking the claims is a pesticidal agent from Xenorhabdus which is active when administered orally. This is not found persuasive because, for example, Claim 1 is drawn to a an insecticidal composition that is adapted for oral administration comprising a pesticidal material from Xenorhabdus species. There is a difference in what is claimed and what is suggested as the special technical feature. For

example the claim reads on a composition that is adapted for oral administration not the pesticidal agent. The prior art reads on such compositions as indicated by the art rejections below.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 15-16 and 21-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 15.

4. Claim 13, 14 and 17-20 (which were not addressed in the restriction) have been included in Group I since upon reconsideration it has been determined that these claims are included within the scope of claim 1. and are examined with claims 1-12.

5. Claims 1-14 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant invention is broadly drawn to an insecticidal composition that comprises a proteinaceous pesticidal compound obtainable from Xenorhabdus. The instant specification provides a nucleic acid sequence of almost 40kb. The specification, for example, indicates that this sequence may contain more than one protein coding sequence that may be insecticidal either

alone or when presented together (see page 3, lines 10-15). The specification does not provide one in the art what the coding sequence may be within this large piece of DNA or what the sequence or structure of the protein or proteins is/are or whether there are in fact two or more proteins that may or may not be needed to provide for an insecticidal activity. The specification only provide rudimentary qualities to extracts such as stability and the retention and loss of activity in filters as different as 40kDa and 100 kDa. Claim 1 is not limited even to the 40kb sequence but reads on any proteinaceous insecticidal protein that may be obtained from any species within Xenorhabdus. One in the art would not know what the structure of such a composition would be based on the general disclosure provided. The specification discloses SEQ ID NO: 1 which corresponds to the cDNA/genomic DNA encoding a proteinaceous pesticidal compound or compounds. The invention is further drawn to encompass proteins that are encoded by gene sequences, sequences that hybridize to SEQ ID NO: 1, corresponding sequences from various species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical

name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Since the instant specification provides only a nucleic acid sequence and does not provide any sequences for the proteinaceous compounds of the claims it is the position of the examiner that an adequate written description of the instant invention is lacking.

6. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of culture medium and cells per se of the Xenorhabdus exemplified as insecticidal compositions, does not reasonably provide enablement for the scope instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant invention is broadly drawn to an insecticidal composition that is adapted for oral delivery and includes a proteinaceous pesticidal material from an Xenorhabdus species and methods of killing or controlling insect pests via such compositions.

The instant specification describes the use of cells and supernatant to kill insects. The instant specification does not disclose the killing of any insect via the ingestion of a proteinaceous compound per se but only shows inhibition of growth and death via cells per se and from supernatant. The instant specification does not provide one in the art with guidance for what specific agent is responsible for the death of insects but teaches only that within a 40kb DNA something or things is encoded that causes death of insects. The instant specification does not show any "adaption" of a compound for oral delivery but only shows the "oral delivery" of cells per se and supernatant from cells. One in the art would not know how to adapt a proteinaceous compound based on the disclosure of the instant application other than delivering cells per se or supernatant form cells. The reasons set forth above under the written description rejection are also incorporated into the instant rejection since on in the art can not use that which is not described.

One in the art would be required to perform undue trial and error experimentation to practice the instant invention. The Quantity of experimentation would include, for example, The determination of methods to "adapt proteinaceous compounds" for oral administration, determine what protein or proteins provide for pesticidal properties (for example is it one protein or a combination of two or more, does the protein itself provide toxicity of does the protein convert some substrate into a toxic substance and is this substrate from the cells per se or from the medium provided for growth?).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

It should be noted for the following rejections that the limitation "adapted for oral administration" has been interpreted to read on the preparation of Xenorhabdus cells and cell cultures *per se* since that is all that the instant specification discloses for such adaption.

8. Claims 1-6, 11, 13, 17, 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Dudney (US 5,616,318).

Dudney discloses the use of Xenorhabdus nematophilus cells and cell cultures (strain ATCC 19061/1) to kill Solenopsis *invicta* via the application of cells and cell cultures (LB broth) to Solenopsis *invicta* mounds. It is noted that in the absence of evidence to the contrary LB broth is considered an argriculturally acceptable carrier. It is noted that a "pesticidal agent" may be a cell per se.

9. Claims 1-5, 13, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Glinski et al (Comparative Biochemistry and Physiology Vol. 85A(4):673-677, 1986).

Glinski et al disclose the killing of G. *mellonella* via feeding of Xenorhabdus *nematophilus* (see page 675, for example). It is noted that a "pesticidal agent" may be a cell per se.

10. Claims 1-5 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Smigielski et al (WO 95/00647).

Smigielski et al disclose a X *nematophilus* protein toxic to insects and disclose that, for example plants can be altered to express such a toxin and also disclose that such a protein can be applied with an acceptable agricultural carrier. A plant that expresses such a toxin is a composition that comprises a X *nematophilus* pesticidal protein and is a food source of any insect that consumes such a plant, for example.

11. Claims 1-3, 5, 6, 17 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by NCIMB deposits 40886 and 40087 as admitted on page 4 of the specification.

The instant specification discloses that these deposits were made 10 July 1997. Applicants priority document 9618083.1 does not disclose these cells. The oral pathogenicity of these cells is inherent especially in view of applicant disclosure that the feeding of these cell kills insects. It is noted that a "pesticidal agent" may be a cell per se.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 7, 8, 9, 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dudney (US 5,616,318), Glinski et al (Comparative Biochemistry and Physiology Vol. 85A(4):673-677, 1986), Smigielski et al (WO 95/00647), and NCIMB deposits 40886 and 40087 as admitted on page 4 of the specification, in view of Cayley et al (US Patent 5,770,192).

The primary references are relied upon as above.

The primary references above do not teach an insecticidal composition that further includes a pesticidal material obtainable from B *thuringiensis.*

Cayley et al have taught toxins from Xenorhabdus and from B *thuringiensis* and specifically endotoxin from B *thuringiensis (see columns 5 and 6, for example)* to be used as

pesticides when expressed from baculovirus vectors that are ingested by insects (see columns 1 and 2, for example) such as Dipteria and Lepidoptera (see column 9, for example) and also assert that it is desirable to use their invention in combination with other biological control agents or chemical insecticides (see column 9, for example).

One in the art would have been motivated to use the baculovirus constructs taught by Cayley et al with any other known biological control agent such as those described by the primary references since it is specifically asserted by Cayley et al to do so. One in the art would have an expectation of success since both biological control agents have been shown to have insecticidal properties.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean McGarry whose telephone number is (703) 305-7028.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. Papers should be faxed to Art Unit 1635 via the PTO Technology Center Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices

published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see C.F.R. 1.6(d)). The Art Unit 1635 FAX number is (703) 308-4242 or (703) 305-3014. NOTE: If Applicant **does** submit a paper by Fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sean McGarry

March 22, 2001

SEAN McGARRY
PRIMARY EXAMINER
TC 1600